IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, Plaintiff, vs. MYLYNN TUFTE, in her official capacity as the State Health Officer of North Dakota; MARK J. HARDY, in his official capacity as the Executive Director of the North Dakota Board of Pharmacy; FRAN GRONBERG, in her official capacity as the President of the North Dakota Board of Pharmacy; and WAYNE STENEHJEM, in his official capacity as the Attorney General of North Dakota, Defendants.	**ORDER GRANTING IN PART AND DENYING IN PART THE PARTIES' CROSS MOTIONS FOR SUMMARY JUDGMENT** Case No.: 1:17-cv-141

Before the Court are cross motions for summary judgment. The Plaintiff, Pharmaceutical Care Management Association ("PCMA") filed its motion for summary judgment on January 19, 2018. See Docket No. 33. The Defendants, Mylynn Tufte, Mark Hardy, Fran Gronberg, and Wayne Stenehjem, in their official capacities (collectively "North Dakota"), filed a response in opposition and a cross-motion for summary judgment on March 9, 2018. See Docket Nos. 38 and 39. PCMA filed a response on April 9, 2018. See Docket No. 40. North Dakota filed a reply on April 23, 2018. See Docket No. 42. With the Court's permission, PCMA filed supplemental authority on July 9, 2018. See Docket No. 44. North Dakota filed a response to PCMA's supplemental authority on July 20, 2018. See Docket No. 50. In light of recent case law, both parties also filed supplemental briefing on July 20, 2018. See Docket Nos. 48 and 49. For the reasons set forth below, the Court grants, in part, each motion for summary judgment and denies, in part, each motion for summary judgment.

I. BACKGROUND

PCMA is a national trade association representing pharmacy benefit managers ("PBMs"), with its principal place of business in Washington, D.C. See Docket No. 1. PBMs are third-party health plan administrators that manage and administer prescription drug benefits on behalf of health insurance plans. See Docket No. 10-3, p. 3. PBMs negotiate prescription drug prices with drug manufacturers and pharmacies, create networks of pharmacies to fill prescriptions, and process and pay insurance claims. See Docket No. 1, p. 4. When an insured patient fills a prescription, the pharmacy generally contacts a PBM to obtain insurance coverage and copayment information. See Docket No. 39-2, p. 6. After the pharmacy fills the prescription, the PBM reimburses the pharmacy based on a rate set out in a contract between the PBM and the pharmacy. See Docket No. 1, p. 6. The PBM then bills the health insurance plan at a rate negotiated between the PBM and the health insurance plan. See Docket No. 39-2, p. 6. In sum, PBMs are intermediaries between patients' and health insurance plans' demand for prescription drugs and manufacturers' and pharmacies' supply of prescription drugs.

In April 2017, North Dakota's governor, Doug Burgum, signed Senate Bills 2258 and 2301 into law. See S.B. 2258, 2017 Leg., 65th Sess. (ND 2017); S.B. 2301, 2017 Leg., 65th Sess. (ND 2017). The laws regulate PBMs and pharmacies. According to North Dakota, the legislation "sought to define the rights of pharmacist in relation to [PBMs], and to regulate certain practices by PBMs." See Docket No. 39-1, p. 2. The legislation contains provisions concerning (1) the practice of pharmacy; (2) pharmacy accreditation and credentialing; and (3) perceived self-dealing and abusive practices on the part of PBMs. The parties contest the validity of various provisions, all of which are summarized below.

A. PROVISIONS CONCERNING THE PRACTICE OF PHARMACY

The legislation contains the following provisions concerning the practice of pharmacy:

- S.B. 2258 §1(7) allows pharmacies to disclose "relevant" information to patients, including "the cost and clinical efficacy of a more affordable alternative drug if one is available," and it prohibits gag orders on such disclosure.

- S.B. 2258 §1(5) allows pharmacies to disclose to patients or plan sponsors information regarding the amount of reimbursement the pharmacy receives after a prescription drug is dispensed.

- S.B. 2258 § 1(8) authorizes pharmacies to "mail or deliver drugs to a patient as an ancillary service of a pharmacy."

- S.B. 2258 § 1(9) bars contracts that prohibit pharmacies from charging patients shipping and handling fees.

- S.B. 2301 § 1(5) authorizes pharmacies to dispense "any and all drugs allowed" under their license.

B. PROVISIONS CONCERNING PHARMACY ACCREDITATION AND CREDENTIALING

The legislation contains the following provisions concerning pharmacy accreditation and credentialing:

- S.B. 2258 §1(11) prohibits PBMs from requiring "pharmacy accreditation standards or recertification requirements inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy in this state."

- S.B. 2301 §1(4) similarly prohibits PBMs from requiring, for participation in a PBM's pharmacy network, "accreditation standards or recertification requirements . . . which are inconsistent with, more stringent than, or in addition to the federal and state requirements for licensure as a pharmacy in this state."

- S.B. 2258 § 1(3) requires PBMS to utilize pharmacy performance standards set by unbiased, nationally recognize entities, and it regulates the fees PBMs may impose based on pharmacy performance standards.

C. PROVISIONS CONCERNING PERCEIVED SELF-DEALING AND ABUSIVE PRACTICES ON THE PART OF PBMS

The legislation contains the following provisions concerning perceived self-dealing and abusive practices on the part of PBMs:

- S.B. 2258 § 1(2) prohibits PBMs and third-party payers from charging pharmacies certain fees, including fees that are imposed after the point of sale, not reported on the remittance advice for a claim, or are not apparent at the time of claim processing.

- S.B. 2258 § 1(4) prohibits copayments that exceed the cost of the medication being purchased, and it bars PBMs from "redact[ing] the adjudicated cost," i.e., the amount the PBM or third-party payer reimburses a pharmacy for a prescription.

- S.B. 2258 §1(10) requires PBMs to disclose certain information about their pharmacy networks "to enable the pharmacy to make an informed contracting decision."

- S.B. 2301 § 1(2) obligates PBMs and third-party payers having ownership interest in a pharmacy to disclose, to plan sponsors, on request, the difference between the amount paid to the pharmacy and the amount charged to the plan sponsor.

- S.B. 2301 § 1(3) prohibits PBMs from having an ownership interest in patient assistance programs or mail-order specialty pharmacy unless the PBM agrees "to not participate in a transaction that benefits the [PBM] . . . instead of another person owed a fiduciary duty."

On July 11, 2017, PCMA filed a complaint against State Health Officer Mylynn Tufte; Executive Director of the North Dakota Board of Pharmacy, Mark J. Hardy; President of the North Dakota Board of Pharmacy, Fran Gronberg; and North Dakota's Attorney General, Wayne Stenehjem. See Docket No. 1. PCMA then filed a motion for a preliminary injunction on July 20, 2017. See Docket No. 10. The Court held a hearing regarding PCMA's motion for preliminary injunction on August 22, 2017. See Docket No. 24. On November 7, 2017, the Court denied

PCMA's motion for a preliminary injunction. See Docket No. 27. Now the Court considers the parties' cross-motions for summary judgment. See Docket Nos. 33 and 38.

II. LEGAL DISCUSSION

PCMA argues the legislation places restrictions and requirements on PBMs that are preempted by the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 *et seq*., and Medicare Prescription Drug Improvement and Modernization Act of 2003 ("Medicare Part D"), 42 U.S.C. § 1395w-101 *et seq*. PCMA seeks this Court's declaration that the legislation is expressly preempted by federal law. In opposition, North Dakota contends the legislation regulates areas of concern that have been excepted from federal regulation. As detailed below, the Court concludes the legislation is not preempted by federal law, save one provision requiring PBMs to disclose certain information to health insurance plans, which the Court finds preempted by an overlapping Medicare Part D standard.

A. STANDARD OF REVIEW

Summary judgment is appropriate when the evidence, viewed in a light most favorable to the non-moving party, indicates no genuine issues of material fact exist and the moving party is entitled to judgment as a matter of law. Davison v. City of Minneapolis, 490 F.3d 648, 654 (8th Cir. 2007); see also Fed. R. Civ. P. 56(a). Summary judgment is not appropriate if there are factual disputes that may affect the outcome of the case under the applicable substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A genuine issue of material fact is not the "mere existence of some alleged factual dispute between the parties." State Auto Ins. Co. v. Lawrence, 358 F.3d 982, 985 (8th Cir. 2004). Rather, an issue of material fact is genuine "if the evidence is

such that a reasonable jury could return a verdict for the nonmoving party." Anderson, 477 U.S. at 248. The moving party always bears the burden of demonstrating the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). The non-moving party may not rely merely on allegations or denials; it must set out specific facts showing a genuine issue for trial. Forrest v. Kraft Foods, Inc., 285 F.3d 688, 691 (8th Cir. 2002). The court must view the facts in the light most favorable to the non-moving party. Adickes v. S.H. Kress & Co., 398 U.S. 144, 157 (1970).

B. THE PREEMPTION DOCTRINE

The preemption doctrine is rooted in the Supremacy Clause, which states federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Because of the Supremacy Clause's mandate, a state law that conflicts with federal law is without effect. Maryland v. Louisiana, 451 U.S. 725, 746 (1981). Courts have delineated two types of preemption: express and implied. See Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992). Express preemption occurs when Congress has "unmistakably ordained" that its enactments alone are to regulate a subject. Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977). Implied preemption occurs when congressional command is implicitly contained in a statute's structure and purpose. Gade, at 98.

Congressional intent is at the base of all preemption analysis. Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516 (1992). Courts must start their inquiry with the assumption that the historic police powers of the States were not meant to be superseded by federal law unless that was the "clear and manifest" intent of Congress. Rice v. Sante Fe Elevator Corp., 331 U.S. 218, 230 (1947); see also Cipollone, at 516. This assumption assures the "federal-state balance will not be

disturbed unintentionally by Congress or unnecessarily by the courts." Jones, 430 U.S. at 525. "[A] high threshold must be met if a state law is to be preempted for conflicting with the purposes of a federal Act." Chamber of Commerce of the U.S. v. Whiting, 563 U.S. 582, 607 (2011) (quoting Gade, 505 U.S. at 110).

C. ERISA PREEMPTION

ERISA comprehensively regulates employee welfare benefit plans that "through the purchase of insurance or otherwise," provide medical, surgical, or hospital care, or benefits in the event of sickness, accident, disability, or death. 29 U.S.C. § 1002(1). ERISA was intended to:

> protect interstate commerce and the interests of participants in employee benefit plans and their beneficiaries, by requiring the disclosure and reporting to participants and beneficiaries of financial and other information with respect thereto, by establishing standards of conduct, responsibility, and obligation for fiduciaries of employee benefit plans, and by providing for appropriate remedies, sanctions, and ready access to the Federal courts.

29 U.S.C. § 1001(b).

"To meet the goals of a comprehensive and pervasive Federal interest and the interests of uniformity with respect to interstate plans, Congress included an express preemption clause in ERISA for the displacement of State action in the field of private employee benefit programs." Minn. Chapter of Associated Builders & Contractors, Inc. v. Minn. Dep't of Pub. Safety, 267 F.3d 807, 810 (8th Cir. 2001). The Supreme Court has described the preemption clause as having "a broad scope, and an expansive sweep," and being "conspicuous for its breadth." California Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 324 (1997) (internal citation omitted).

The scope of ERISA preemption has left courts "deeply troubled." Prudential Ins. Co. of America v. Nat'l Park Med. Ctr. Inc., 154 F.3d 812, 815 (8th Cir. 1998). Courts have struggled to

reconcile the sweeping language of ERISA's preemption clause with the assumption that Congress does not intend to bar state action in fields of traditional state regulation or historic police powers. See New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 654-55 (1995) ("we have never assumed lightly that Congress has derogated state regulation, but instead have addressed claims of pre-emption with the starting presumption that Congress does not intend to supplant state law."). The Supreme Court has warned that ERISA's preemption clause must not be read to "extend to the furthest stretch of its indeterminacy." De Buono v. NYSA-ILA Med. and Clinical Services Fund, 520 U.S. 806, 813 (1997).

The preemption clause specifically provides that ERISA "shall supersede any and all State laws insofar as they may now or hereafter *relate to* any employee benefit plan[.]" 29 U.S.C. § 1144(a) (emphasis added). "Yet, Congress did not define what it meant by state laws that 'relate to' an ERISA benefit plan anywhere in the statute." Prudential, 154 F.3d at 819. The Supreme Court has "endeavored with some regularity to interpret and apply the 'unhelpful text' of ERISA's pre-emption provision." Dillingham, 519 U.S. at 324 (quoting Travelers Ins. Co., 514 US at 656). The Court's endeavor has resulted in a two-part test. ERISA preempts state laws that (1) include a reference to ERISA plans, or (2) have an impermissible connection with ERISA plans. Gobeille v. Liberty Mut. Ins. Co., 136 S.Ct. 936, 943 (2016).

1. WHETHER S.B. 2258 AND S.B. 2301 INCLUDE A REFERENCE TO ERISA PLANS

Neither S.B. 2258 nor S.B. 2301 contain an explicit reference to ERISA or ERISA plans. ERISA is not mentioned, discussed, defined, or excluded in either bill. However, PCMA argues that both S.B. 2258 and S.B. 2301 contain "implicit" references to ERISA because, within each

bill, the terms *pharmacy benefit manager*, *third-party payer*, and *plan sponsor* are defined broadly enough to implicate ERISA health plans. See Docket No. 33-1, pp. 16-18.

Under the "reference to" inquiry, the Supreme Court has preempted state laws that (1) imposed requirements by reference to ERISA covered programs; (2) specifically exempted ERISA plans from an otherwise generally applicable statute; and (3) premise a cause of action on the existence of an ERISA plan. Prudential, 154 F.3d at 822. An impermissible reference to ERISA occurs when a state law "acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation[.]" Gobeille, 136 S.Ct. at 943 (internal citation and quotation omitted).

PCMA cites the Eighth Circuit Court of Appeals decision in *Pharmaceutical Care Management Association v. Gerhart* for the proposition that a general state-law reference broad enough to encompass ERISA plans must result in preemption. 852 F.3d 722 (8th Cir. 2017). In PCMA's words: "A statute that implicitly refers to ERISA plans, such as by including 'health benefit plans' within its scope, has a prohibited reference to ERISA plans." See Docket No. 33-1, p. 16. In *Gerhart*, PCMA sued the state of Iowa seeking a declaration that an Iowa state law regulating how PBMs established generic drug pricing was preempted by ERISA. Id. at 726. The Eighth Circuit held the Iowa statute contained an impermissible reference to ERISA. Id. at 729-30. The court noted that, by its "express terms," the Iowa law "specifically exempts certain ERISA plans from its otherwise general application." Id. at 729. The court held that "[b]ecause of this impermissible reference to ERISA or ERISA plans, [the Iowa law] is preempted under 29 U.S.C. § 1144(a)." Id. at 730. The court also noted the law contained an "implicit reference" to ERISA because it regulated PBMs that administer benefits for plans subject to ERISA. Id. at 729.

The Eighth Circuit recently commented on the *Gerhart* holding in *Pharmaceutical Care Management Association. v. Rutledge*, 891 F.3d 1109 (8th Cir. 2018). The court stated:

> The state argues that Gerhart should be limited to its consideration of the Iowa Act's "express reference" to ERISA, and that Gerhart's "implicit reference" analysis is dicta inconsistent with Supreme Court precedent. We disagree. In addition to finding that Iowa Code § 510B.8 had a prohibited express reference to ERISA, the Gerhart court found that the "Iowa law also makes implicit reference to ERISA through regulation of PBMs who administer benefits for 'covered entities,' which, by definition, include health benefit plans and employers, labor unions, or other groups 'that provide[ ] health coverage.' These entities are necessarily subject to ERISA regulation." 852 F.3d at 729.

Id. at 1112 (alteration in original).

PCMA argues the decisions in *Gerhart* and *Rutledge* establish a new rule regarding the "reference to" inquiry. See Docket No. 48, p. 8 ("*Rutledge* confirmed that an implicit reference to ERISA exists even where the law does not *only* regulate entities necessarily subject to ERISA regulation.") (emphasis in original). However, the rule PCMA attempts to distill from *Gerhart*—that a general state-law provision broad enough to encompass ERISA plans within its scope constitutes an implicit reference to an ERISA plan—would vastly expand the scope of the ERISA preemption doctrine. The Court finds nothing in the Eight Circuit's analysis to indicate such an intent. The *Rutledge* court explained *Gerhart* is not "inconsistent with the Supreme Court's precedent in Travelers or De Buono . . . ." 891 F.3d at 1112. Those cases require preemption under the "reference to" inquiry when a state law (1) acts "immediately and exclusively" on ERISA plans, or (2) when the existence of an ERISA plan is "essential to the law's operation." Gobeille, 136 S.Ct. at 943 (alteration in original) (quoting Dillingham, 519 U.S. at 325).

Reading any state-law definition broad enough to include ERISA plans within its scope to constitute an impermissible "implicit" reference to ERISA would extend the preemption clause "to the furthest stretch of its indeterminacy." De Buono, 520 U.S. at 813. For example, North

Dakota's definition of "organization" includes, among others, "any legal or commercial entity," N.D.C.C. § 1-01-49(5), and would "by definition" include "entities [that] are necessarily subject to ERISA regulation." Gerhart, 852 F.3d at 729. The United States Supreme Court has rejected this type of "uncritical literalism" in applying the ERISA preemption clause. See Gobeille, 136 S.Ct. at 943 (quoting Travelers, 514 U.S. at 656). As such, regarding the "reference to" analysis the Court must conduct, it will apply the test set out in *Dillingham* and refined by its progeny: "[w]here a State's law acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation . . ., that 'reference' will result in pre-emption." Gobeille, at 943 (alteration in original) (quoting Dillingham, 519 U.S. at 325).

i. NORTH DAKOTA'S DEFINITION OF "PHARMACY BENEFITS MANAGER"

PCMA argues North Dakota's definition of "pharmacy benefits manager" includes entities that provide services to ERISA plans, and thus the definition constitutes an impermissible reference to ERISA. See Docket No. 33-1, pp. 16-17. The legislation provides that "pharmacy benefit manager," as used within each bill, has the same definition as set out in N.D.C.C. § 19-03.6-01 (dealing with pharmacy records audits). See S.B. 2258 § 1(1)(a) and S.B. 2301 § 1(1)(a); see also N.D.C.C. §§ 19-02.1-14.2(1)(d) and 19-02.1-16.1(1)(a). "Pharmacy benefits manager" is defined as:

> [A] person that performs pharmacy benefits management and includes any other person acting for such person under a contractual or employment relationship in the performance of pharmacy benefits management for a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payer, or health program administered by a state agency.

See N.D.C.C. § 19-03.6-01(4).

It is conceivable that a "pharmacy benefits manager" could provide services to an insurance plan, and that the insurance plan could be subject to ERISA. But that is one outcome of many, and more importantly, one not expressed in the legislation's language. A state law impermissibly references ERISA when it "acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation[.]" Gobeille, 136 S.Ct. at 943. North Dakota's definition of "pharmacy benefits manager" includes entities that contract with a broad range of parties. Although insurance plans may be one of these parties, the definition makes no distinction as to whether an insurance plan is subject to ERISA. The Court finds the legislation does not impermissibly reference ERISA plans by way of North Dakota's definition of pharmacy benefits manager.

ii. NORTH DAKOTA'S DEFINITION OF "THIRD-PARTY PAYER"

PCMA argues North Dakota's definition of "third-party payer" impermissibly includes ERISA plans within its scope. See Docket No. 33-1, pp. 16-17. The legislation provides that the term "third-party payer," as used within each bill, has the same definition as in N.D.C.C. § 19-03.6-01. See S.B. 2258 § 1(1)(c) and S.B. 2301 §1(1)(d); see also N.D.C.C. § 19-02.1-16.1(1)(c). "Third-party payer" is defined as "an organization other than the patient or health care provider involved in the financing of personal health services." N.D.C.C. § 19-03.6-01(6). The definition clearly applies to a broad range of entities that have no relation to ERISA. The legislation, by way of North Dakota's definition of third-payer, neither "acts immediately and exclusively upon ERISA plans" nor is the "existence of ERISA plans essential to the law's operation." Gobeille, 136 S.Ct. at 943. The Court finds no impermissible reference to ERISA in North Dakota's definition of third-party payer.

iii. NORTH DAKOTA'S DEFINITION OF "PLAN SPONSOR"

PCMA argues North Dakota's definition of "plan sponsor" impermissibly references ERISA plans. PCMA specifically cites the definition's inclusion of the term "employee benefit plan," which includes ERISA plans within its scope. See Docket No. 33-1, p. 18. The legislation provides that "plan sponsor," as that term is used within each bill, has the same definition as in N.D.C.C. § 19-03.6-01. See S.B. 2258 § 1(1)(b) and S.B. 2301 § 1(1)(b); see also N.D.C.C. § 19-02.1-16.1(1)(b). That provision defines "plan sponsor" as "the employer in the case of an *employee benefit plan* established or maintained by a single employer, or the employee organization in the case of a plan established or maintained by an employee organization . . . or other similar group that establishes or maintains the plan." See N.D.C.C. § 19-03.6-01(5) (emphasis added). PCMA contends that because the reference to "employee benefit plan" encompasses ERISA covered plans, it constitutes an impermissible implicit reference to an ERISA plan. See Docket No. 33-1, p. 18.

PCMA's argument is without merit. The legislation uses the term "plan sponsor" to either allow pharmacies, or require PBMs, to disclose certain information to, among others, the sponsors of plans. See S.B. 2258 § 1(5) (allowing pharmacies to disclose information to plan sponsors and patients regarding drug reimbursement amounts); S.B. 2301 § 1(2) (requiring PBMs to disclose the difference between amounts paid to pharmacies and amounts charged to plan sponsors for prescription drugs). However, the plans referenced in the definition of "plan sponsors" may or may not be subject to ERISA, and thus the law still has purpose absent ERISA applicability. See e.g. 29 U.S.C. §§ 1003(b) and 1144(a) (exempting government-sponsored plans, church-sponsored plans, workmen's compensation plans, and other types of plans from ERISA regulation and preemption). In other words, the legislation makes no distinction between ERISA and non-ERISA

plans, and it applies equally to both. Thus, it does not constitute an impermissible reference to ERISA or ERISA plans.

In sum, PCMA's arguments regarding the scope of certain terms and definitions oversimplifies the issue. The "reference to" inquiry concerns the law's implications on ERISA plans—i.e., whether the law "acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation[.]" Gobeille, 136 S.Ct. at 943 (internal citation and quotation omitted). North Dakota's law does neither, and thus the Court finds no impermissible reference to ERISA.

2. WHETHER THE LEGISLATION HAS AN IMPERMISSIBLE CONNECTION WITH ERISA PLANS

Because the Court finds that neither bill includes a "reference to" ERISA, the Court continues its preemption analysis under the "connection with" prong. A state law has an impermissible "connection with" ERISA plans when it "governs . . . a central matter of plan administration" or "interferes with nationally uniform plan administration." Gobeille, 136 S.Ct. at 943. PCMA's arguments largely focus on PBMs' relationships with ERISA plans. PCMA asserts the legislation's imposition of requirements on PBMs necessarily affects PBMs' ability to provide services to ERISA plans. Thus, PCMA's logic continues, the legislation's limitations on PBMs have impermissible downstream effects on ERISA plans and plan administration. See Docket No. 33-1, pp. 20-21. In response, North Dakota emphasizes the legislation's relationship to the practice of pharmacy—an area normally left to state regulation. See Docket No. 49, p. 10.

Both parties also disagree as to how the Eighth Circuit Court of Appeals' recent decisions in *Gerhart* and *Rutledge* bear on the "connection with" analysis this Court must conduct. *Gerhart* involved an Iowa law that regulated how PBMs establish generic drug pricing and also mandated

disclosure of PBMs' maximum allowable cost ("MAC") methodology.[1] 852 F.3d at 726. The Eighth Circuit found the establishment of MAC lists and generic drug reimbursement rates to be matters central to plan administration, and it concluded Iowa's regulation of MAC calculations interfered with nationally uniform plan administration. Id. at 731. Similarly, in *Rutledge*, PCMA challenged an Arkansas law mandating PBMs follow certain practices with regard to MAC methodology. 891 F.3d at 1111. The Eighth Circuit affirmed the district court's conclusion that the Arkansas law interferes with uniform plan administration because it "regulates PBMs in ways fundamentally similar to the Iowa statute in *Gerhart* . . . ." 240 F. Supp. 3d. 951, 958 (E.D. Ark. 2017); 891 F.3d at 1112-1113;. While illustrative, the Court does not find either *Gerhart* or *Rutledge* necessarily dispositive of this case as the parties suggest. North Dakota's legislation does not mandate any specific practice regarding MAC methodology or reimbursement rates. Rather, the legislation contains provisions regulating the practice of pharmacy and pharmacy accreditation standards, provisions addressing disclosure obligations, and prohibitions on certain post point-of-sale fees that may be levied on pharmacies. Thus, the Court will examine the specifics of North Dakota's law to determine whether it (1) governs matters central to plan administration, or (2) interferes with nationally uniform plan administration. See Gobeille, 136 S.Ct. at 943.

i. WHETHER THE LEGISLATION GOVERNS MATTERS CENTRAL TO PLAN ADMINISTRATION

A state law that governs matters central to ERISA plan administration is preempted by ERISA. Gobeille, 136 S.Ct. at 943. "Obligations undertaken with plan administration include

[1] Maximum allowable cost lists detail the amount a PBM is willing to reimburse a pharmacy for the purchase of a generic prescription drug. Each PBM uses its own methodology to determine these reimbursement rates and to create maximum allowable cost lists. Gerhart, at 726.

'determining the eligibility of claimants, calculating benefit levels, making disbursements, monitoring the availability of funds for benefit payments, and keeping appropriate records in order to comply with applicable reporting requirements.'" Gerhart, 852 F.3d at 730 (quoting Fort Halifax Packing Co. Inc., v. Coyne, 482 U.S. 1, 9 (1987)). Neither bill contains any provisions concerning claimant eligibility determinations, the monitoring of funds for benefit payments, or the keeping of appropriate records for reporting requirements. Rather, the legislation limits the supplanting of state pharmacy licensing requirements, see e.g. S.B. 2258 § 1(11); S.B. 2301 § 1(4), addresses conflicts occurring in the provision of pharmacy services in North Dakota, see e.g. S.B. 2301 § 1(3), authorizes North Dakota pharmacies to engage in certain practices, see e.g. S.B. 2258 §§ 1(7), (8), and (9); S.B. 2301 § 1(5), and imposes disclosure obligations and post point-of-sale fee limitations, see e.g. S.B. 2258 §§ 1(2) and (4). In short, the legislation largely regulates pharmacy services, certain fees, and communication between pharmacies, their customers, and PBMs. The Court finds neither bill governs a matter central to ERISA plan administration.

ii. WHETHER THE LEGISLATION INTERFERES WITH NATIONALLY UNIFORM PLAN ADMINISTRATION

A state law that interferes with nationally uniform plan administration is preempted by ERISA. Gobeille, 136 S.Ct. at 943. PCMA argues the legislation will impose a variety of burdens and expenses upon PBMs, the imposition of which will have a downstream effect on ERISA plans. The legislation's incidental effect on plans, PCMA asserts, will result in interference with nationally uniform plan administration. See Docket No. 33-1, pp. 20-21. The Court does not doubt that, like other state healthcare regulation, the legislation will have some effect on healthcare plans. For example, the legislation places various requirements on PBMs that may result in PBMs losing certain revenues or incurring expenses. See, e.g., S.B. 2258 §§ 1(2) and (9) (prohibiting

PBMs from levying post point-of-sale fees on pharmacies and requiring disclosure of pharmacy network information to enable pharmacies to make informed contracting decisions). PBMs may attempt to recoup these lost revenues and expenses by passing costs on to plans. These increased costs could potentially affect plans' decision-making. But this effect is too tenuous to constitute interference with nationally uniform plan administration. "[I]f ERISA were concerned with any state action—such as medical-care quality standards or hospital workplace regulations—that increased costs of providing certain benefits, and thereby potentially affected the choices made by ERISA plans, [the Court] could scarcely see the end of ERISA's pre-emptive reach, and the words 'relate to' would limit nothing." Dillingham, 519 U.S. at 329.

PCMA's arguments fail to bridge the gap between the legislation and interference with plan administration—let alone nationally uniform plan administration. Put another way, PCMA has not explained how the alleged effects of the legislation will change how ERISA plans are administered. To be sure, PCMA has explained, in detail, how the legislation will force PBMs to modify their business practices. See, e.g., Docket Nos. 33-3, 33-4, and 33-5. But it has not articulated a change in custom or practice that the legislation requires ERISA plans to make. A state law interferes with nationally uniform plan administration when it subjects plans to different requirements in different states. See Egelhoff, 532 U.S. at 148. North Dakota's law does not impose any requirements on ERISA plans. Consequently, the Court finds the legislation does not interfere with nationally uniform plan administration.

D. MEDICARE PART D PREEMPTION

Having determined the legislation is not preempted by ERISA, the Court turns to the parties' arguments concerning Medicare Part D preemption. In regards to Medicare, Congress has

proclaimed: "The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [Part D] plans which are offered by [Part D] organizations under this part." 42 U.S.C. § 1395w-26(b)(3); see also 42 U.S.C. § 1395w-112(g) (applying Part C's preemption provision to Part D). "The federal scheme preempts a state law when (1) Congress or the Centers for Medicare and Medicaid Services (CMS) has established 'standards' in the area regulated by the state law; and (2) the state law acts 'with respect to' those standards." Rutledge, 891 F.3d at 1113 (citing § 1395w-26(b)(3)). "For purposes of the preemption provision, a standard is a statutory provision or a regulation promulgated under [Medicare] and published in the Code of Federal Regulations." New York City Health and Hospitals Corp. v. WellCare of New York, Inc., 801 F. Supp. 2d 126, 140 (S.D.N.Y. 2011) (quoting Med. Card Sys., Inc., v. Equipo Pro Convalecencia, 587 F. Supp. 2d 384, 387 (D.P.R. 2008)); see also Uhm v. Humana, Inc., 620 F.3d 1134, 1148 n. 20 (9th Cir. 2010).

According to CMS, the agency responsible for regulating Medicare Part D plans, Part D preemption occurs "only when CMS actually creates standards in the area regulated. To the extent we do not create any standards whatsoever in a particular area, we do not believe preemption would be warranted." Federal Regulations for Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,320 (January 28, 2005). For preemption to occur, "[c]onflict between the state law and the federal standard is unnecessary." Rutledge, 891 F.3d at 1113.

Medicare's preemption provision contains a savings clause that expressly prohibits federal interference with state regulation of the practice of medicine: "Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided . . . ." 42 U.S.C. §

1395. In addition, the Medicare preemption provision expressly exempts "State licensing laws or State laws relating to plan solvency" from its scope. 42 U.S.C. § 1395w-26(b)(3).

PCMA argues nearly every provision of the legislation is preempted by Medicare Part D. North Dakota asserts none are preempted. The Court will address each contested provision in the following order: (1) provisions concerning the practice of pharmacy; (2) provisions regarding accreditation and credentialing requirements; and (3) provisions directed at perceived abusive practices and PBM self-dealing. But first the Court turns to PCMA's preliminary argument that three specific Medicare provisions generally preempt any state regulation of contracts between PBMs and pharmacies.

1. PCMA'S GENERAL PREEMPTION ARGUMENT

PCMA first argues 42 U.S.C. § 1395w-104, which provides beneficiary protections for prescription drug coverage, preempts any state regulation of contracts between pharmacies and Part D plans. See Docket Nos. 33-1, p. 36 and 40, p. 46. PCMA specifically points to Section 1395w-104(b)(1)(A), requiring Part D plans to "permit the participation of any pharmacy that meets the terms and conditions under the plan." PCMA argues that because of this standard "a Part D Sponsor need not contract with a pharmacy that does not meet those terms and conditions; if a pharmacy wishes to participate in a plan sponsor's network, it has no choice but to accept the plan's 'terms and conditions.'" See Docket No. 33-1, p. 36. Thus, PCMA contends the legislation "interfere[s] with that standard by preventing North Dakota's pharmacies from accepting the plan's 'terms and conditions.'" See Docket No. 33-1, p. 36. First, the Court disagrees with PCMA's characterization of this standard, i.e. that it was meant to give pharmacies "no choice but to accept the plan's 'terms and conditions.'" See Docket No. 33-1, p. 36. The standard ensures

patients have ready access to pharmaceutical services—hence its title: "Access to covered part D drugs—assuring pharmacy access—Participation of any willing pharmacy." 42 U.S.C. § 1395w-104(b)(1)(A); see also Rutledge, 891 F.3d at 1114 (characterizing the standard as setting "forth requirements with regard to Medicare recipients' access to pharmacies"). Moreover, this standard has no bearing on the negotiation and contracting process between pharmacies and PBMs. The Court finds Section 1395w-104(b)(1)(A) does not overlap with North Dakota's regulation of contracts between pharmacies and PBMs, and thus it does not preempt the legislation.

PCMA similarly argues 42 C.F.R. § 423.505, which provides certain requirements for contracts between CMS and Part D plan sponsors, preempts any state regulation of contracts between pharmacies and PBMs. See Docket Nos. 33-1, p. 37 and 40, p. 46. PCMA specifically cites Section 423.505(b)(18) requiring Part D plans to agree "to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy . . . ." This standard parallels 42 U.S.C. § 1395w-104, discussed directly above, to ensure Part D beneficiaries have access to pharmaceutical services. Moreover, it only applies to contracts "between the Part D plan sponsor and CMS." Section 423.505(a). The Court concludes this provision does not preempt the legislation's regulation of contracts between PBMs and pharmacies.

Last, PCMA argues the Medicare Part D "non-interference clause" preempts all state regulation of contracts between PBMs and pharmacies. See Docket Nos. 33-1, p. 38; 40, pp. 26-27; and 48, p. 11. The clause provides:

> In order to promote competition under this part and in carrying out this part, the Secretary –
>
> (1) may not interfere with negotiations between drug manufacturers and pharmacies and PDP sponsors; and

> (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

42 U.S.C. § 1395w-111(i). By its plain terms, the clause prohibits the Secretary of the United States Department of Health and Human Services from interfering in certain areas. However, the Eighth Circuit Court of Appeals has interpreted the clause to prohibit "both federal *and state* interference in negotiations between Part D sponsors and pharmacies . . . ." Rutledge, 891 F.3d at 1113 (emphasis added). PCMA argues "every challenged provision of [the legislation] interferes in contract negotiations between plan sponsors/PBMs and pharmacies by mandating or proscribing outcomes on issues that would otherwise be bargained for." See Docket No. 33-1, p. 38.

PCMA's argument—that the non-interference clause creates a type of general field preemption of state regulation on PBM contracts—is unpersuasive. First, *Rutledge* did not decide the preliminary issue of whether the non-interference clause even applies to PBM-related regulation. By its plain terms, the clause prohibits interference between "drug manufactures and pharmacies and PDP sponsors." 42 U.S.C. § 1395w111(i)(1). And thus *Rutledge* did not hold, as PCMA suggests, that any and all state regulation of contract negotiations between pharmacies and PBMs is preempted by Medicare Part D. Rather than finding the non-interference clause creates a type of field preemption, *Rutledge* explained: "The federal scheme preempts a state law when (1) Congress or [CMS] has established 'standards' in the area regulated by the state law; and (2) the state law acts 'with respect to' those standards." Rutledge, at 1113. *Rutledge* then went on to examine specific Medicare Part D standards and concluded the state laws at issue were preempted because they acted "with respect to" the Part D Standard. See Rutledge, at 1113-1114 (finding Arkansas laws regulating the price of retail drugs and allowing pharmacies to decline to dispense drugs were preempted by the Medicare Negotiated Price Standard and the Medicare Pharmacy Access Standard). Given the Eighth Circuit's recent analysis in *Rutledge*, the Court concludes

Section 1395w111(i) does not bar states from all regulation of PBM contracts. Accordingly, as instructed by *Rutledge*, the Court will examine each provision of the legislation to determine (1) if Congress or CMS has established a standard in the area regulated; and (2) whether the state regulation acts with respect to those standards. Id. at 1113. The Court concludes all but one provision survive Medicare Part D analysis.

2. PROVISIONS CONCERNING THE PRACTICE OF PHARMACY

The legislation contains various provisions regulating the practice of pharmacy. It contains provisions: (1) allowing pharmacies to dispense any drug they are licensed to dispense; (2) allowing pharmacies to disclose pricing information to patients; and (3) allowing pharmacies to mail or deliver drugs to patients. As detailed below, the Court finds these provisions, which regulate the practice of pharmacy in North Dakota, are not preempted by Medicare Part D. They do not act with respect to a Medicare standard, and even if they did, they regulate the practice of medicine and thus fall within the scope of the Medicare savings clause. See 42 U.S.C. § 1395 ("Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided").

i. PHARMACIES MAY DISPENSE ANY DRUG ALLOWED BY THEIR LICENSE

The legislation provides: "A licensed pharmacy or pharmacist may dispense any and all drugs allowed under that license." S.B. 2301 § 1(5). PCMA suggests this provision acts with respect to CMS's standards concerning formularies. PCMA argues: "[T]his provision would bar the use of formularies. A formulary is a list of drugs that a Part D plan covers. CMS extensively

regulates the development and use of formularies. . . . Allowing North Dakota to ban formularies deliberately undermines CMS's contemplation, regulation, and approval of them." See Docket No. 33-1, p. 47. The Court disagrees. This provision allows pharmacies to dispense drugs in a manner consistent with their licenses. It has no bearing on whether a drug may be listed on a formulary, and it contains no language banning formularies or compelling Part D plans to cover any drugs. The Court finds PCMA's arguments unavailing.

ii. PHARMACY DISCLOSURE OBLIGATIONS

The legislation contains two provisions regarding pharmacy disclosure obligations. It first contains a provision concerning the disclosure of information regarding drug efficiency and cost:

> A pharmacy or pharmacist may provide relevant information to a patient if the patient is acquiring prescription drugs. This information may include the cost and clinical efficacy of a more affordable alternative drug if one is available. Gag orders of such a nature placed on a pharmacy or pharmacist are prohibited.

S.B. 2258 § 1(7). The legislation also contains a provision allowing pharmacies to disclose reimbursement amounts they receive:

> A pharmacy or pharmacist may disclose to the plan sponsor or to the patient information regarding the adjudicated reimbursement paid to the pharmacy which is compliant under the federal Health Insurance Portability and Accountability Act of 1996 . . . .

S.B. 2258 § 1(5). In support of preemption, PCMA asserts CMS has developed standards concerning what information must be disclosed to plan beneficiaries. PCMA cites to various provisions identifying plan sponsors' disclosure obligations to beneficiaries. See Docket No. 40, p. 53; see also 42 U.S.C. § 1395w-104(a)(1) and (a)(2) (setting forth annual disclosure obligations plan sponsors must provide to plan enrollees); 42 U.S.C. § 1395w-104(k) (plan sponsors must ensure pharmacies inform plan enrollees of "any differential between the price of the drug to the

enrollee and the price of the lowest priced generic covered part D drug under the plan"). However, North Dakota's law does not speak to *plan sponsor* disclosure obligations. Rather, it sets forth disclosure obligations for *pharmacies*. Thus, it does not overlap with the standards PCMA cites. Moreover, it falls squarely within the savings clause for regulations concerning the manner in which medical services are provided. See 42 U.S.C. § 1395.

iii. DRUG DELIVERY SERVICES

The legislation also authorizes pharmacies to mail or deliver drugs to patients: "A pharmacy or pharmacist may mail or deliver drugs to a patient as an ancillary service of a pharmacy." S.B. 2258 § 1(8). A related provision allows pharmacies to charge shipping and handling fees: "A pharmacy benefits manager or third-party payer may not prohibit a pharmacist or pharmacy from charging a shipping and handling fee to a patient requesting a prescription be mailed or delivered." S.B. 2258 § 1(9). In support of preemption, PCMA cites standards that "contemplate the existence of mail-order pharmacies that are distinct from retail pharmacies." See Docket No. 33-1, p. 44; see also 42 C.F.R. § 423.120(a)(1) (authorizing Part D sponsors to charge beneficiaries higher cost-sharing amounts for using retail pharmacies instead of mail-order pharmacies). PCMA also cites the definition of "dispensing fees," which includes "pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee." 42 C.F.R. § 423.100. Although the standards PCMA relies on might "contemplate the existence" of mail order pharmacies, they do not regulate mail order pharmacy services like North Dakota's law. Thus, there is no overlap between the legislation and the federal standards. And even if there was, the Court finds the legislation's provisions regarding drug

delivery services constitutes a regulation concerning the manner in which medical services are provided under the Medicare savings clause. See 42 U.S.C. § 1395.

3. PROVISIONS REGARDING PHARMACY ACCREDITATION AND CREDENTIALING REQUIREMENTS

The legislation contains provisions concerning two areas of pharmacy accreditation and credentialing. First, it contains provisions prohibiting PBMs from imposing accreditation requirements that are stricter than state and federal law. Second, the legislation requires PBMs to utilize benchmarks set by an unbiased, nationally-recognized entity when evaluating pharmacy performance, and it regulates the fees PBMs may levy on pharmacies due to deficient performance. As detailed below, the Court finds none of these provisions overlap with a CMS standard. Further, to the extent any did, they would fall under the Medicare preemption provision's exception for state laws concerning licensing. See 42 U.S.C. § 1395w-26(b)(3) (Medicare standards supersede any state law or regulation "other than State licensing laws"); see also 42 U.S.C. § 1395w-112(g) (applying Part C's preemption provision to Part D).

i. IMPOSITION OF ACCREDITATION REQUIREMENTS

With respect to PBMs' imposition of accreditation requirements on pharmacies, the legislation provides:

> A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or recertification requirements inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy in this state.

S.B. 2258 § 1(11). The legislation also regulates the accreditation requirements pharmacies must satisfy to participate in PBM networks:

> A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or certification requirements to participate in a network which are inconsistent with, more stringent than, or in addition to the federal and state requirements for licensure as a pharmacy in this state.

S.B. 2301 § 1(4).

In support of preemption, PCMA points to federal standards requiring Part D sponsors to have quality assurance arrangements that ensure cost-efficiency, avoid adverse drug interactions, and mitigate medication errors. See Docket No. 33-1, p. 40; see also 42 U.S.C. § 1395w-104(c); 42 C.F.R. § 423.153(c). PCMA asserts these standards go "above and beyond state pharmacy licensing" and that CMS has "reserved for itself the role of partnering with private industry to identify the optimum performance measures." See Docket No. 33-1, p. 40. However, as explained below, the regulation of pharmacy practice standards has been left to the states, and CMS has not imposed any pharmacy accreditation standards. In fact, the same standard PCMA cites requires Part D sponsors to ensure pharmacies "comply with minimum standards for pharmacy practice as established by the States." 42 C.F.R. § 423.153(c)(1). CMS has explained in its commentary:

> It has been our longstanding policy to leave the establishment of pharmacy practice standards to the states, and we do not intend to change that now. We continue to believe pharmacy practice standards established by the states provide applicable minimum standards for all pharmacy practice standards, and § 423.153(c)(1) requires representation that network providers are required to comply with minimum standards for pharmacy practice as established by the states.

Medicare Policy and Technical Changes; Contract Year 2019, 82 Fed. Reg. 56,336-01, 56,411 (Nov. 28, 2017) (to be codified at 42 C.F.R. pts. 405, 417, 422, 423 and 498).

After seeking public comment on various proposed rules, CMS indicated it does not intend to regulate pharmacy accreditation standards:

> Several commenters provided that accreditation is best performed by an independent, third-party actor . . . . Several commenters believed that CMS should establish accreditation standards, and that CMS approval should be the only requirement for acceptance of accreditation . . . . Many commenters contended

> neither Part D plan sponsors nor PBMs may arbitrarily exclude pharmacies utilizing other nationally recognized accreditation organizations, and that Part D plan sponsors/PBMs should not be able to mandate the use of particular accreditation organizations.
>
> [. . . .]
>
> While we did not propose specific accreditation standards, we will consider it in the future if we find that our current requirements are no longer sufficient . . . . While CMS appreciates the commenters' concerns that accreditation is best performed by an independent, third-party actor, we did not consider such a policy change in the proposed rule and would need to consider the issue further.

Medicare Policy and Technical Changes; Contract Year 2019, 83 Fed. Reg. 16,440-01, 16,597-598 (Apr. 16, 2018) (to be codified at 42 C.F.R. pts. 405, 417, 422, 423 and 498). In this same commentary, CMS specifically addressed a comment concerning North Dakota's accreditation provision:

> Comment: A commenter provided that North Dakota and New Hampshire have enacted laws prohibiting PBMs from requiring additional accreditation other than the requirement of the applicable state board of pharmacy. Another commenter offered that they have seen situations where state standards are insufficient, unenforced, or unmonitored.
>
> Response: CMS thanks the stakeholder for this information, and encourages commenters to keep us apprised of such examples. However, at present, we continue to believe state pharmacy practice acts represent a reasonably consistent minimum standard of practice.

Id. at 16,598. Although the Court owes no deference to CMS, the agency does have a unique understanding of the Medicare statutes, and the Court may consider its commentary. See Wyeth v. Levine, 555 U.S. 555, 576-77 (2009) (although agencies generally have no authority to pronounce on preemption, their unique understanding of the statutes they administer gives them an ability to make determinations about how state requirements may impact the federal regulatory scheme); see also Uhm, 620 F.3d at 1155. As CMS has explained, accreditation and licensing are areas of regulation that have been left to the states. Because CMS has not promulgated standards

in this area, the Court finds North Dakota's legislation concerning pharmacy accreditation requirements is not preempted by Medicare Part D.

ii. PHARMACY PERFORMANCE BENCHMARKS

The legislation also requires PBMs to utilize benchmarks set by an unbiased, nationally-recognized entity when evaluating pharmacy performance, and it regulates the fees PBMs may levy on pharmacies due to their deficient performance. Section 1(3) of S.B. 2258 provides as follows:

> 3. Pharmacy performance measures or pay for performance pharmacy networks shall utilize the electronic quality improvement platform for plans and pharmacies or other unbiased nationally recognized entity aiding in improving pharmacy performance measures.
>
> a. A pharmacy benefits manager or third-party payer may not collect a fee from a pharmacy if the pharmacy's performance scores or metrics fall within the criteria identified by the electronic quality improvement platform for plans and pharmacies or other unbiased nationally recognized entity aiding in improving pharmacy performance measures.
>
> b. If a pharmacy benefits manager or third-party payer imposes a fee upon a pharmacy for scores or metrics or both scores and metrics that do not meet those established by the electronic quality improvement platform for plans and pharmacies or other nationally recognized entity aiding in improving pharmacy performance measures, a pharmacy benefits manager or third-party payer is limited to applying the fee to the professional dispensing fee outlined in the pharmacy contract.
>
> c. A pharmacy benefits manager or third-party payer may not impose a fee relating to performance metrics on the cost of goods sold by a pharmacy.

S.B. 2258 § 1(3). PCMA argues this provision is preempted by the same federal standards cited above, which require Part D plan sponsors to have quality assurance arrangements that ensure cost-efficiency, avoid adverse drug interactions, and mitigate medication errors. See Docket No. 33-1,

pp. 39-41; see also 42 U.S.C. § 1395w-104(c); 42 C.F.R. § 423.153(c). The Court rejects this argument for the same reasons articulated above. CMS has not articulated pharmacy practice standards. Rather, Part D sponsors must take measures to ensure pharmacies "comply with minimum standards for pharmacy practice as established by the States." 42 C.F.R. § 423.153(c)(1). North Dakota's legislation sets a standard for pharmacy performance by articulating the benchmarks that may be used to measure pharmacy performance—i.e., the "electronic quality improvement platform for plans and pharmacies" or "other unbiased nationally recognized entity aiding in improving pharmacy performance measures." S.B. 2258 § 1(3). The Court concludes S.B. 2258 § 1(3) is not preempted.

4. PROVISIONS CONCERNING SELF-DEALING AND ABUSIVE PRACTICES

North Dakota's law contains various provision directed at perceived self-dealing and abusive practices on the part of PBMs. The legislation (1) prohibits PBMs from levying certain fees and charges on pharmacies and patients; (2) imposes disclosure obligations on PBMs; and (3) prohibits PBMs that own mail-order or specialty pharmacies from engaging in self-dealing. As articulated below, the Court finds the bulk of the law not preempted, save one provision requiring PBMs to disclose certain information to plans, which the Court finds preempted by an overlapping Medicare Part D standard.

i. REGULATION OF FEES AND CHARGES

The legislation provides the following prohibitions on post point-of-sale fees:

> 2. A pharmacy benefits manager or third-party payer may not directly or indirectly charge or hold a pharmacy responsible for a fee related to a claim:

a. That is not apparent at the time of claim processing;

b. That is not reported on the remittance advice of an adjudicated claim; or

c. After the initial claim is adjudicated at the point of sale.

S.B. 2258 § 1(2). PCMA argues CMS has enacted "intricate standards" concerning post point-of-sale fees. See Docket No. 40, p. 56. PCMA points to standards that contemplate post point-of-sale fees in reconciliation calculations used to determine the amounts Part D sponsors "actually pay" for prescription drugs.[2] See Docket No. 40, pp. 56-57; see e.g. 42 C.F.R. § 423.308 (defining "direct and indirect remuneration" to include retroactive fees). PCMA suggests North Dakota's law alters the Part D reconciliation scheme by "banning retroactive fees." See Docket No. 40, p. 57. PCMA argues the legislation "would nullify part of the standard concerning what makes up a negotiated price and would change the calculation of payments made by CMS to plans during the reconciliation process by removing retroactive fees from the equation." See Docket No. 40, p. 57. The Court finds PCMA's argument unpersuasive. The legislation regulates the imposition of fees levied on pharmacies that are related to claims for prescription drugs. It does not overlap with, nor does it alter, the calculations used in the reconciliation process. PCMA has not pointed to any federal standard concerning PBMs' imposition of fees on pharmacies. The Court finds S.B. 2258's provision regulating post point-of-sale fees is not preempted by Medicare Part D.

PCMA also argues the legislation's regulation of copayments is preempted. The legislation provides the following concerning copayments:

[2] PCMA explains the reconciliation process: "CMS requires sponsors and PBMs to report post point-of-sale fees to CMS by requiring them to report amounts 'actually paid' for the drugs and the [remuneration] a plan has received. . . . The amounts reported by plans and PBMs factor into payments by CMS. At the end of a contract year, through a reconciliation process, CMS makes final reinsurance and risk corridor payments to Part D sponsors based on the amounts 'actually paid' by the Part D sponsor for the provision of the Part D benefit." See Docket No. 40, pp. 56-57.

> A pharmacy benefits manager or third-party payer may not charge a patient a copayment that exceeds the cost of the medication. If a patient pays a copayment, the dispensing provider or pharmacy shall retain the adjudicated cost and the pharmacy benefits manager or third-party payer may not redact the adjudicated cost.

S.B. 2258 § 1(4). PCMA argues this provision overlaps with federal standards that set copayment amounts for certain drugs. See Docket No. 33-1, pp. 41-42; see also 42 C.F.R. § 423.104(d)(5)(i). PCMA suggests that retainment of copayments is "an entitlement that CMS has granted to plans." See Docket No. 33-1, p. 42. The Court disagrees. The standards PCMA cites may set copayment amounts, but they do not specify which entity is entitled to retain copayments as does North Dakota's law. PCMA also argues there are federal standards accounting for "direct and indirect remuneration" to plans after a prescription drug has been sold, which may include copayment amounts. See Docket No. 33-1, p. 42; see also 42 C.F.R. § 423.308. However, these standards, which account for various fees and payments, also do not mandate the allocation of certain payments to certain parties. The Court finds North Dakota's regulation of copayments is not preempted by Medicare Part D.

ii. DISCLOSURE OBLIGATIONS

The legislation contains two provisions concerning PBM disclosure obligations. The first provision requires PBMs to disclose information about PBM pharmacy networks to pharmacies. According to North Dakota, this provision was intended to help pharmacies evaluate the profitability of PBM contracts by providing pharmacies with information detailing the number of patients that would be subject to a PBM contract's reimbursement policies. See Docket No. 39-1, p. 10. The provision states:

> Upon request, a pharmacy benefits manager or third-party payer shall provide a pharmacy or pharmacist with the processor control number, bank identification

> number, and group number for each pharmacy network established or administered by a pharmacy benefits manager to enable the pharmacy to make an informed contracting decision.

S.B. 2258 § 1(10). The second disclosure provision obligates PBMs with an ownership interest in a pharmacy to disclose, to plan sponsors, the difference between the amount paid to a pharmacy and the amount charged to the plan sponsor. It states:

> If requested by a plan sponsor contracted payer, a pharmacy benefits manager or third-party payer that has an ownership interest, either directly or through an affiliate or subsidiary, in a pharmacy shall disclose to the plan sponsor contracted payer any difference between the amount paid to a pharmacy and the amount charged to the plan sponsor contracted payer.

S.B. 2301 § 1(2).

In support of preemption, PCMA cites various federal standards discussing PBMs' disclosure obligations to beneficiaries, CMS, and plan sponsors. See Docket No. 33-1, pp. 42-43; see also 42 U.S.C. §§1395w-104(a)(1)-(2) (setting forth annual disclosure obligations plan sponsors must provide to plan enrollees); 42 U.S.C. §§1395w-104(k) (plan sponsors must ensure pharmacies inform plan enrollees of "any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan"); 42 U.S.C. § 1320b-23 (requiring PBMs to disclose information regarding drug sales and pricing to CMS); 42 C.F.R. § 423.514(d) (detailing reporting requirements for pharmacy benefits manager data to plan sponsors and CMS).

PCMA does not cite any federal standard, and the Court is not aware of any, that concerns the disclosure of information by PBMs to pharmacies. Because CMS has not promulgated standards in this area, the Court finds S.B. 2258 § 1(10), which requires the disclosure of PBM pharmacy network information to pharmacies, is not preempted by Medicare Part D. However, the Court agrees with PCMA regarding S.B. 2301's PBM disclosure obligations to plan sponsors.

Federal standards specifically require PBMs to provide information to plan sponsors, including the number of prescriptions dispensed, the amount of rebates, discounts, or price concessions the PBM negotiates and passes through to the plan sponsor, and the difference between the amount the PBM pays the pharmacy and the plan sponsor. See 42 C.F.R. § 423.514(d); 42 U.S.C. § 1320b-23. Senate Bill 2301 § 1(2), which requires certain PBMs to report to plan sponsors "any difference between the amount paid to a pharmacy and the amount charged to the plan sponsor" overlaps with this standard, and thus the Court finds it is preempted as applied to Medicare Part D plans.[3]

iii. PBM SELF DEALING

The legislation also contains a provision aimed at potential self-dealing on the part of PBMs that own pharmacies. It states:

> A pharmacy benefits manager or a pharmacy benefits manager's affiliates or subsidiaries may not own or have an ownership interest in a patient assistance program and a mail order specialty pharmacy, unless the pharmacy benefit manager, affiliate, or subsidiary agrees to not participate in a transaction that benefits the pharmacy benefits manager, affiliate, or subsidiary instead of another person owed a fiduciary duty.

S.B. 2301 §1(3). In support of preemption, PCMA cites 42 C.F.R. § 423.501, which defines "related entity" as any entity that is related to a PDP sponsor by common ownership or control and performs some of a plan's management functions, furnishes services to a plan enrollee, or leases or sells property to a plan. See Docket No. 33-1, p. 45. PCMA also points to a study and CMS manuals and publications that address potential conflicts of interest in the dispensing of

[3]The Court's holding does not invalidate the remainder of the legislation. North Dakota has enacted a broad severability clause. When a court finds any portion of a law invalid, "such judgment does not affect, impair, nor invalidate any other clause, sentence, paragraph, chapter, section or part . . . ." N.D.C.C. § 1-02-20. The parties do not dispute the validity or applicability of North Dakota's severability clause.

prescription drugs. See Docket No. 33-1, pp. 46-48. PCMA argues: "CMS and North Dakota address the same problem but chose a different means to protect against it. As such, [S.B. 2301 § 1(3)] is preempted because CMS and North Dakota regulate the same conduct." See Docket No. 40, p. 60.

However, the manuals, publication, and study CMS cites are not standards. "[A] standard is a statutory provision or a regulation promulgated under [Medicare] and published in the Code of Federal Regulations." New York City Health and Hospitals Corp., 801 F. Supp. 2d at 140 (quoting Med Card Sys., Inc., 587 F. Supp. 2d at 387); see also Uhm, 620 F.3d 1148 n. 20. The one standard PCMA cites simply defines the term "related entity." See 42 C.F.R. § 423.501. This definitional provision does not regulate PBM conflicts of interest in any way. Because the legislation's provision concerning PBM self-dealing does not overlap with a Medicare Part D standard, the Court finds it is not preempted.

III. CONCLUSION

The Court has carefully reviewed the entire record, the parties' filings, and the relevant law. For the reasons set forth above, the Plaintiff's motion for summary judgment (Docket No. 33) is **GRANTED IN PART AND DENIED IN PART**. The Defendants' cross-motion for summary judgment (Docket No. 38) is also **GRANTED IN PART AND DENIED IN PART**.

IT IS SO ORDERED

Dated this 5th day of September, 2018.

/s/ Daniel L. Hovland
Daniel L. Hovland, Chief Judge
United States District Court